510 (K) Summary of Hy-Chlo™ Wound Solution

AUG 2 1 2012

510(K) Summary	This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.
Submitter Company	Patrin Pharma, Inc P.O. Box 1481 7817 Babb Avenue, Suite 103 Skokie, IL 60076-1481
Contact	Jay S. Trivedi Director, New Products Tel: (847) 644-1321 Fax: 800-936-3088 Email:
Date Prepared	November 8th, 2011
Device Trade/Brand Name	Hy-Chlo™ Wound Solution
Device Common Name	Wound Solution,
Classification Name	Dressing, Wound, Drug
Device Classification	Jet Lavage
Product Code Proposed	FQH
Device Description	Hy-Chlo™ Wound Solution is an aqueous, clear, colorless solution that cleans open wounds. The solution delivers sodium hypochlorite as a preservative with sodium bicarbonate as a pH modifier. Hy-Chlo™ Wound Solution will be supplied in heat sealed, impervious, mold extruded HDPE bottles. A permanent affixed label will be on each bottle.
Indications for Use	
OTC	Hy-Chlo™ Wound Solution is intended for removal of foreign objects such as dirt, for cleansing of minor cuts, lacerations, abrasions and wounds.
Professional Use	Hy-Chlo™ Wound Solution is intended to be used under the supervision of healthcare professional in the cleansing of acute, chronic and/or open wounds such as Stage I-IV pressure ulcers, diabetic foot and leg ulcers, surgical wounds, first and second degree burns and grafted and donor sites.
General use conditions	Hy-Chlo™ Wound Solution is to be used for patients with acute or chronic wounds generally in an attended healthcare setting such as acute and non-acute care hospitals, nursing homes, surgery centers, emergency rooms and wound clinics
Manufacturing and Performance Testing	Hy-Chlo™ Wound Solution will be manufactured in USA in an FDA inspected facility inspected as recently as 2011. The manufacturing and testing will be performed under cGMP (Current Good Manufacturing Practices) and Good Laboratory Practices (GLP) guidance and according to

	Laboratory Practices (GLP) guidance and according to specifications set per current United States Pharmacopia (USP). Manufacturing practices incorporate a QbD (quality by design) analysis that addresses all critical parameters for consistent and measurable product quality that meets or exceeds established specifications. A testing regimen and associated release specifications have been established per USP (United States Pharmacopeia) to meet Hy-Chlo™ Solution testings. All production batches are tested prior to release to insure product meets established specifications and is safe and effective for its intended use. Pre-marketing stability studies have been performed to demonstrate continued stability and efficacy of the product for the claimed shelf life. Ongoing performance and stability studies are planned for continued monitoring.

Device Description

	Proposed
Devices	Hy-Chlo™ Wound Solution
Indications of Use	OTC: Hy-Chlo™ Wound Solution is intended for removal of foreign objects such as dirt and for cleaning of minor cuts, lacerations, abrasions and wounds. Professional Use: Hy-Chlo™ Wound Solution is intended to be used under the supervision of healthcare professional for removal of foreign objects such as dirt and for cleaning of minor cuts, lacerations and abrasions.
Dispensing	OTC
General Use Conditions	Patients with acute or chronic wounds generally in an attended healthcare setting such as acute and non-acute care hospitals, nursing homes, surgery centers, emergency rooms and wound clinics
Ingredients	Purified Water, Sodium Bicarbonate, Sodium Hydroxide, Sodium Hypochlorite 0.125% weight/volume
pH	9-11
Organoleptic properties	Mild Chlorine odor; colorless
Non-Clinical Performance	Shelf life- 1 year and will be extended up to 2 years with real time data.
Manufacturing	Manufacturing under cGMP in a FDA inspected plant and testing performed under GLP.
Warnings	• For External Use Only • Keep out of reach of children • If swallowed, contact Poison Center or seek immediate medical attention • If redness, swelling, irritation or pain appears or increases, contact doctor immediately • Do not use if sensitive to chlorine

Testing Summary:

Overall, in vivo studies conducted demonstrate that Hy-Chlo™ wound solution (0.125% sodium hypochlorite) is safe, non-irritant and non- sensitizer and did not inhibit the healing process. Hy-Chlo wound solution is also effective mold, yeast and S. aureus, E. coli, P. aeruginosa, C. albicans, S. aureus (MRSA), A. Brasiliensis. Testing also confirmed that Hy-Chlo™ wound solution delivers the required force to remove dirt and foreign objects from the wound.

In-vitro study was conducted under ISO 10993 with Mammalian cell line (L-929) with Hy-Chlo Wound solution, 0.125%. Based on the grading criteria in ANSI/AAMI/ISO 10993-5:2009, Hy-Chlo™ Wound solution, 0.125% had a moderate reactivity for cytotoxicity per qualitative evaluation of the cells exposed. However, a follow up in vivo study conducted to study wound healing in young adult pigs, the results clearly show that Patrin Pharma's Sodium Hypochlorite solution, 0.125% did not inhibit the normal healing process (see below).

In vivo, acute dermal abrasion study was conducted in the dorsal area of young adult pigs over 14 days. Each animal wound was treated every day with 1 ml of Hy-Chlo™ Wound Solution (0.125% Sodium Hypochlorite solution) for 14 days. Each animal was observed every day for healing process and compared with the untreated site. Daily treatment of the abraded sites with Sodium Hypochlorite solution (0.125%) did not inhibit the healing process when compared with untreated abrasion sites. Local infection was not observed.

In-vivo study was conducted in rabbits for dermal irritation with Hy-Chlo wound solution for 4 hours and 24 hours exposure. The results indicated that with 4 hour contact exposure in abraided skin, there was minimal irritation with the irritation clearing within 24 hours. For 24 hours of contact exposure to abraded skin, there was minimal irritation with the irritation clearing up within 72 hours. No skin irritation reactions were observed in the unabraded sites. Thus, in accordance with the OPPTS Guidelines, Hy-Chlo™ Wound Solution, 0.125% would not be considered to be a dermal irritant.

In-vivo study conducted in guinea pigs for sensitization clearly demonstrated that sensitization of naïve group was not significantly different indicating that there was no sensitization.

Preservative testing was conducted for Hy-Chlo™ Wound Solution (0.125%) using USP protocol. The microorganisms tested were S. aureus, E. coli, P. aeruginosa, C. albicans, S. aureus (MRSA), A. Brasiliensis, mold and yeast. Results clearly indicate that Hy-Chlo™ wound Solution is effective against all of the organisms.

Hy-Chlo™ wound solution was used to estimate the maximum force at the site of administration. The purpose of the study was to measure the forces and estimate the maximum pressure exerted at the site of contact by a plume of Hy-Chlo wound solution that is expelled from the container. It is important that force generated is sufficient to be able to remove dirt and foreign objects from the wound. The results indicate that force generated was 8.0 psi (sd 0.7). The force is well within the typical ranges of 4-15 psi for such applicators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Patrin Pharma, Incorporated
% Mr. Jay S. Trivedi
Director of New Products
P.O. Box 1481
Skokie, Illinois 60076

AUG 2 1 2012

Re: K113312
Trade/Device Name: HyChlo™ Wound Solution
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II
Product Code: FQH
Dated: July 30, 2012
Received: August 6, 2012

Dear Mr. Trivedi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number: K113312

Device Name: HyChlo™ Wound Solution

Indications for Use:

OTC	HyChlo™ Wound Solution is intended for removal of foreign objects such as dirt, for cleansing of minor cuts, lacerations, abrasions and wounds.
Professional Use	HyChlo™ Wound Solution is intended to be used under the supervision of healthcare professional in cleansing of acute, chronic and/or open wounds such as Stage I-IV pressure ulcers, diabetic foot and leg ulcers, surgical wounds, first and second degree burns and grafted and donor sites.

Prescription Use X AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113312